### **REMARKS**

Reconsideration and the timely allowance of the pending claims, in view of the following remarks, are respectfully requested.

In the pending Office Action, the Examiner rejected: claims 1-12 under 35 U.S.C. § 112, first paragraph, for scope of enablement; claim 5 under 35 U.S.C. § 112, first paragraph, for lack of enablement; claims 1-12 under 35 U.S.C. § 112, second paragraph, as being indefinite; claims 1 and 3 under 35 U.S.C. § 102(b), as being anticipated by U.S. Pat. No. 5,861,415 to Majeed et al. (hereinafter "the '415 patent"); claim 5 under 35 U.S.C. § 103(a), as being unpatentable over the '415 patent in view of "Antioxidant Effects of Tea" or Applicant's specification; claims 1-12 under 35 U.S.C. § 103(a), as being unpatentable over WO 99/20289 to Oppenheim et al. (hereinafter "the '289 patent application") in view of "Antioxidant Effects of Tea" or Applicant's specification; claims 1-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Pat. No. 6,391,364 to Lindsay (hereinafter "the '364 patent") or claim 1 of U.S. Pat. No. 6,264,995 to Newmark et al. (hereinafter "the '995 patent").

Prior to the entry of this Amendment, claims 1-12 were submitted for examination. By this Amendment, Applicants have amended claims 1, 3, 5 and 6 to provide a clearer presentation of the claimed invention, without new matter being introduced. Accordingly, claims 1-12 are submitted for examination, of which claims 1 and 8 are independent.

Applicants respectfully traverse the rejections and the reasons for the rejections under 35 U.S.C. §§ 102, 103, 112 and the judicially created doctrine of obviousness-type double patenting, for at least the reasons presented below.

### 1. Rejection of Claims 1-12 Under 35 U.S.C. § 112, ¶ 1

Claims 1-12 were rejected under 35 U.S.C. § 112, first paragraph, for scope of enablement. The Examiner reported that Applicants' specification enabled a supercritical extract process. The Examiner, however, reported that Applicants' specification does not reasonably enable the employment of "any" supercritical extract process. The Examiner also reported that it is unclear what is a "supercritical" extract. Applicants respectfully traverse the rejection.

The specification need not explicitly teach those in the art to make and use the invention, the enablement requirement is met if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without undue experimentation. Applicants' specification sets forth at least one mode of making and using the claimed invention, as the Examiner reported. Applicants' claims 1-12 recite, in combination with other limitations, a supercritical extract process. Indeed, one skilled in the art knows how to make and use a supercritical extract process.

Applicants' specification cites, as an example of the art, a publication entitled "Dense Gases for Extraction and Refining" by E. Stahl, K.-W. Quirin and D. Gerard that describes a plurality of well-known supercritical extraction processes. (Applicants' Specification, page 9, lines 13-16). In addition, the Examiner herself cited the '995 patent that further describes another plurality of well-known supercritical extraction processes. ('995 patent, col. 8, lines 44-47). The '995 patent, for example, cited U.S. Pat. Nos.

5,932,101 and 5,120,558 as disclosing known supercritical extraction processes. ('995 patent, col. 8, line 48 to col. 9, line 25).

Applicants invite the Examiner to review Applicants' specification and the above-cited references to better understand what is a supercritical extract process, which is well-known in the art. In one well-known exemplary implementation of a supercritical extract process, the process uses a natural gas, heats the gas to a temperature over (or "super") the "critical" point of the gas, and the gas is then compressed. The "critical" point of a gas is that temperature point over which the gas will maintain its gaseous state and not turn to a liquid. The compressed gas may have the density of a liquid, and may penetrate into a plant and dissolve lipophilic constituents of the plant. The pressure may then be released, and an extract is left.

Applicants respectfully submit that the rejection of claims 1-12 under 35 U.S.C. §

112, first paragraph, has been fully addressed, and the specification at least teaches those in the art that they can make and use the claimed invention without undue experimentation.

### 2. Rejection of Claim 5 Under 35 U.S.C. § 112, ¶ 1

Claim 5 was rejected under 35 U.S.C. § 112, first paragraph. Claim 5, however, has been amended to clarify the claimed invention. Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, has been fully addressed, and amended claim 5 is in proper form for allowance.

### 3. Rejection of Claims 1-12 Under 35 U.S.C. § 112, ¶ 2

### A. <u>Claims 1-12</u>

Claims 1-12 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner reported that the claims are unclear as to what may be considered as "a supercritical extract" process.

As explained above, the term "a supercritical extract" process is clear. Applicants respectfully submit that the rejection under 35 U.S.C. § 112, second paragraph, has been fully addressed, and claims 1-12 are in proper form for allowance.

### B. Claim 6

Claim 6 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner reported that the expression a "period of time" in claim 6 is not defined in the specification. Applicants' specification, however, describes that an exemplary period of time may be "at least four weeks." (Applicants' specification, page 7, lines 19-20).

Claim 6, however, has been amended to clarify the claimed invention. Applicants respectfully submit that the rejection under 35 U.S.C. § 112, second paragraph, has been fully addressed, and claim 6 is in proper form for allowance.

### 4. Rejection of Claims 1 and 3 Under 35 U.S.C. § 102(b)

Claims 1 and 3 were rejected under 35 U.S.C. § 102(b) as being anticipated by the '415 patent. Applicants respectfully traverse the rejection because the '415 patent fails to disclose, teach or suggest all the features recited in the rejected claims.

Amended independent claim 1 requires a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric. In distinction, the Examiner reported

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that the '415 patent discloses a composition containing merely curcuminoids from an extract of turmeric using methanol, which, according to the Examiner, is a known hydroalcoholic solvent.

Clearly, the '415 patent does not disclose a composition by a plurality of extract processes (e.g., a <u>dual</u> extract) of turmeric. The composition of claim 1 by the plurality of extract processes of turmeric, unlike the composition of the '415 patent by a mere single extract process of turmeric using methanol, may then be highly concentrated, chemical-solvent free, undamaged by heat or chemical stress and/or rich with the healing and protective turmeric oils, resins, and curcuminoids. The composition of claim 1 is not the same as or obvious from the composition of the '415 patent.

Thus, the features of amended claim 1 are not disclosed by the '415 patent. As such, Applicants respectfully submit that the '415 patent fails to teach each and every limitation recited in the rejected independent claim, as well as its dependent claims, and therefore cannot be construed as anticipating Applicants' claims.

The '415 patent does not explicitly or inherently disclose each and every limitation of Applicants' claimed invention. Moreover, the '415 patent includes no suggestion for modifying its composition as to change its configuration to include the claimed features, and therefore cannot be construed as rendering obvious the claimed invention.

Thus, independent claim 1 is allowable. In addition, its dependent claims are allowable for reasons of their dependencies, as well as their additional limitations.

Applicants respectfully request that the rejection of claims 1 and 3 under 35 U.S.C. § 102 be withdrawn.

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# 5. Rejection of Claim 5 Under 35 U.S.C. § 103(a)

Claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the '415 patent in view of "Antioxidant Effects of Tea" or Applicants' specification. The Examiner reported that the prior art does not disclose the composition of the '415 patent further including an aqueous extract of green tea. The Examiner also reported that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of the '415 patent to include an aqueous extract of green tea as taught by "Antioxidant Effects of Tea" or Applicant's specification, since, according to the Examiner, "all active composition components . . . [in those cited references] are known to be useful to treat and prevent Alzheimer's disease." Applicants respectfully traverse the rejection and the reasons for the rejection.

Amended claim 5 depends from independent claim 1. As noted above, independent claim 1 has been shown to be allowable. Accordingly, amended claim 5 is also allowable because of its dependency, as well as its additional limitations. Applicants respectfully request that the rejection of claim 5 under 35 U.S.C. § 103 be withdrawn.

# 6. Rejection of Claims 1-12 Under 35 U.S.C. § 103(a)

Claims 1-12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the '289 patent application in view of "Antioxidant Effects of Tea" or Applicant's specification. The Examiner reported that the '289 patent application discloses a composition containing an extract of turmeric containing merely curcuminoids, an extract of green tea, an extract of parsley seed, an extract of rosemary, and an extract of ginger. The Examiner also reported that the '289 patent application discloses extraction processes for herbal plants using solvents. The Examiner reported that the prior art does

not disclose the effective amounts of active agents in the claimed composition. The Examiner, however, reported that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the effective amounts of active agents to achieve the claimed composition. Applicants respectfully traverse the rejection because the '289 patent application, "Antioxidant Effects of Tea" and/or Applicants' "Description of the Background" fails to disclose, teach or suggest all the features recited in the rejected claims.

Applicants' claims 1-12 require a composition comprising at least a supercritical extract and a hydroalcoholic extract of turmeric. In distinction, the Examiner reported that the '289 patent application discloses a composition containing merely curcuminoids from an extract of turmeric using a solvent.

Clearly, the cited references, analyzed individually or in combination, do not disclose, teach or suggest any of the compositions of Applicants' claims 1-12. For example, the composition of independent claims 1 and 8 is produced by at least a supercritical extract and a hydroalcoholic extract of turmeric and therefore, unlike the composition of the '289 patent application, may be highly concentrated, chemical-solvent free, undamaged by heat or chemical stress and/or rich with the healing and protective turmeric oils, resins, and curcuminoids. The composition of claims 1-12 is not the same as or obvious from the composition of the cited references, analyzed individually or in combination.

Thus, independent claims 1 and 8 are allowable. In addition, their dependent claims are allowable for reasons of their dependencies, as well as their additional limitations. For example, the claimed combinations of herbs, extract processes and/or

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amounts of herb extracts are not taught or suggested by the cited references. The Examiner overlooks the fact that "obvious to try" is not the standard of 35 U.S.C. § 103. Applicants respectfully request that the rejection of claims 1-12 under 35 U.S.C. § 103 be withdrawn.

## 7. Rejection of Claims 1-4 Under Double Patenting

Claims 1-4 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the '364 patent or claim 1 of the '995 patent. The Examiner reported that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other." Applicants respectfully traverse the rejections and the reasons for the rejections.

First, the legal standard of double patenting applies <u>only</u> to the claims of a patent and a patent application if they have: (i) the same inventive entity, or (ii) a common assignee, or (iii) overlapping inventive entities. The claims of the '364 patent and Applicants' patent application do <u>not</u> have any of those conditions. The inventor of the '364 patent is Robert C. Lindsay of Whole Flavors, whereas the inventors of Applicants' patent application are Thomas Newmark and Paul Schulick, both of New Chapter. Thus, Applicants submit that the double patenting rejection is improper based on the legal standard of double patenting.

Second, claim 1 of the '995 patent is drawn to a composition including about 13% by weight of an alcoholic, aqueous, a hydroalcoholic extract or a supercritical carbon dioxide of turmeric. By contrast, Applicants' claims 1-4 require a composition by at least a supercritical extract and a hydroalcoholic extract of turmeric. As such, the composition of Applicants' claims 1-4, unlike the composition of the '995 patent, may be highly

concentrated, chemical-solvent free, undamaged by heat or chemical stress and/or rich with the healing and protective turmeric oils, resins, and curcuminoids. Thus, Applicants submit that the double patenting rejection is improper because Applicants' claims 1-4 are not obvious in view of claim 1 of the '995 patent (or claim 1 of the '364 patent).

Claims 1-4 are allowable.

#### 8. <u>Conclusion</u>

In view of the above, the claims are now believed to be in form for allowance, and such an action is hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, she is requested to telephone the undersigned at the number below.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached Appendix is captioned "Versions with markings to show changes made."

Respectfully submitted,

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Enclosure: Appendix

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### **APPENDIX**

## **VERSIONS WITH MARKINGS TO SHOW CHANGES MADE**

### **IN THE CLAIMS:**

The claims are amended as follows:

- 1. (Amended) A composition comprising:

  a supercritical extract and a hydroalcoholic extract of turmeric[,

  wherein a composition is made of effective amounts of the supercritical
  extract and the hydroalcoholic extract of turmeric to effect smoke detoxification in a
  human.]
- 3. (Amended) The composition of claim 1, wherein the composition includes effective amounts of the supercritical extract and the hydroalcoholic extract of turmeric so as to effect smoke detoxification in a human [the composition includes at least one of curcuminoids, antioxidants, and turmerone.]
  - 5. (Amended) The composition of claim 1, further comprising an aqueous extract of green tea[,

wherein at least one of the supercritical extract and the hydroalcoholic extract of turmeric is synergistic in combination with the aqueous extract of green teal.

6. (Amended) The composition of claim 1, wherein an effective amount of the composition is orally administered[, for a therapeutically effective period of time,] to the human exposed to toxins from smoke.